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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/184,043	11/02/1998	HANS HORNAUER	P564-8023	3802

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EXAMINER

CEPERLEY, MARY

ART UNIT PAPER NUMBER

1641

DATE MAILED: 01/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/184,043

Applicant(s)

HORNAUER ET AL

Examiner

Mary (Molly) E. Ceperley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 October 2002 and 13 November 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14 and 60-77 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14 and 60-77 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

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**1)** At the personal interview of November 29, 2002, applicants' attorney stated that he would provide a discussion on the record of Dr. Weiss' explanation (as presented at the interview) of the alleged differences between the applied prior art and the instant invention and would include a discussion of the schematic diagram presented by Dr. Weiss which showed alleged differences between the claimed invention and the applied prior art. Neither a record of Dr. Weiss' discussion nor the schematic drawing discussed at the interview <sup>has</sup> ~~have~~ been provided.

Applicants have also not addressed the inconsistency noted in paragraph **1)c)** of the September 20, 2002 advisory action with regard to the schematic of the Herron '492 method filed with the September 03, 2002 response. Page 5, the second full paragraph, of the October 31, 2002 response refers to this schematic but does not address the inconsistency noted by the examiner.

**2)** In the interest of advancing prosecution, applicants are urged to fully consider the scope of independent claim 14. Applicants should recognize that this claim is inclusive of the use of a solid phase on which the "conjugate of a poly(C<sub>2</sub>-C<sub>3</sub>)-alkylene oxide and an analyte-specific reactant" is "immobilized" by any method. This method is readable on methods which use PEO/PPO-analyte conjugates which may be immobilized by any method and which include methods which use additional reagents such as ethylenediamine and glutaraldehyde as described in the cited prior art. See also, instant claim 64 which uses "covalent coupling".

**3)** In claims 64 and 65, the spelling of the term "binding" should be corrected.

**4)** Although specific claims are cited in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

**5)** The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**6)** Claim 63 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, i.e. as containing new matter. As set forth in paragraph **1)b)** of the September 20, 2002 advisory action, applicants have not provided any indication of where support in the specification may be found for the "preformed" conjugate of newly presented claim 63. Applicants must also describe support in the specification for the limitations of newly presented claims 60-62 and 64-77.

**7)** Claims 14 and 60-77 are again rejected under 35 U.S.C. 112, first paragraph, for the reason stated in paragraph **4)** of the May 31, 2002 final Office action as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants have provided no discussion of support for the "test reagent".

**8)** The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**9)** Claims 60-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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✓ **a)** Claims 64 and 65 are indefinite and confusing in that they recite "the solid phase is immobilized" while independent claim 14 recites that the "conjugate" is immobilized on the solid phase.

2 **b)** In claim 66, there is no antecedent basis in claim 14 for the term "a conjugate of the modified solid phase reactant with the second partner of the binding pair". See also, claim 68: "the modified analyte specific solid phase reactant".

2 **c)** In claims 68 and 69, it is unclear what is meant by the terms "a further alkylene oxide modified binding molecule" and "non-analyte specific molecules". What are the required features/structures of the "molecule"?

2 **d)** In claim 73, it is unclear what is meant by the term "an alkylene oxide modified analyte specific reactant....in combination with an alkylene oxide modified blocker". What is the chemical nature of these two entities and what configuration do they have relative to the other required components of the solid phase of claim 14?

**e)** In claim 77, it is unclear what is meant by the term "test areas containing different analyte-specific solid phase reactants" and it is unclear how these areas are related spatially to the other elements of the support of claim 14. Are the "different analyte-specific solid phase reactants" of claim 77 the same as the "conjugates" of claim 14?

✓ **f)** In claim 60, it is unclear what is meant by the term "an analyte-specific modified solid phase reactant". This term does not appear in instant claim 14 and it is not clear how the "reactant" is "used".

✓ **g)** Claim 61 incorrectly characterizes the "modified solid phase reactant" as being "antibodies, antigens, nucleic acids, ...lectins", terms which would appear to define the "reactant that interacts with the analyte".

**10)** The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

**11)** The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**12)** Claims 14 and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by each of Herron et al (US 5,512,492) or Herron et al (US 5,677,196) for the reasons of record.

A set forth in paragraph **5)** of the May 31, 2002 Office action, the Herron et al patents describe a solid phase on which a PEG-analyte conjugate is immobilized and the use of this solid phase in an assay for the corresponding specific binding pair member of the analyte. See Herron et al ('196): Example III, col. 16, lines 38-45, wherein activated/modified PEG (e.g. PEG-ED<sub>2</sub>) was immobilized on a silica support and wherein the other ED moiety was bound to an aldehyde moiety of an antibody or antibody fragment thus forming a silica-PEG-Ab solid phase which is the same as the solid phase of instant claim 14; Herron

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et al ('492): col. 4, lines 2-12 wherein a silanized support is coated with PEG derivatized with ethylenediamine groups, these groups are reacted with Fab' capture molecules and this support is further used in a sandwich-type assay. The Herron et al method uses the "covalent coupling" of instant claim 64.

Applicants' arguments concerning this rejection, filed in the October 31, 2002 response, have been fully considered but they are not persuasive. The comments which appear in paragraph **2)** above, which discuss the scope of claim 14, directly rebut applicants' position that the method of instant claim 14 is not anticipated by the Herron et al patents.

**13)** Claims 60-77 are rejected under 35 USC 103 as being obvious over each of Herron et al (US 5,512,492) or Herron et al (US 5,677,196).

The Herron et al patents are applied for the reason stated in the above rejection set forth in paragraph **12)**. The features of the dependent claims are either specifically described by the references (e.g., for the "an analyte-specific modified solid phase reactant" of claim 61 defined as containing an "antibody" as one component of a specific binding pair, see Herron et al ('196), col. 16, lines 43-45) or constitute obvious variations in parameters which are routinely modified in the art (e.g. conjugating PEG to a member of a specific binding pair prior to applying the conjugate to the surface (instant claim 63) versus forming the PEG conjugate in situ (Herron et al)) and which have not been described as critical to the practice of the invention.

**14)** Claims 14 and 64 are rejected under 35 U.S.C. 102(b)/(e) as being anticipate by each of Caldwell et al. US 5,516,703 or US 6,284,503.

Each of the references describes a method of detection of an analyte which involves the use of a solid phase upon which is immobilized a conjugate of a member of a specific binding pair with PEG. This is the same solid phase used in instant claim 14. The immunoassay methods of the references which use immobilized PEG-specific binding member conjugates anticipate the method of instant claim 14. See

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Caldwell et al ('703): col. 9, lines 18-35; Examples 5 and 6; Caldwell et al ('503): col. 8, line 65 – col. 9, line 10; col. 16, 6.6.3.1 Immunoassays; col. 17, lines 24-27; claim 1. Caldwell et al use the "covalent coupling" of instant claim 64. The comments made in paragraph **2)** above are pertinent to this rejection.

**15)** Claims 60-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of Caldwell et al. US 5,516,703 or US 6,284,503.

✓ The Caldwell et al patents are applied for the reason stated in paragraph **14)** above. The features of the dependent claims are either specifically described by the references (e.g., for the "an analyte-specific modified solid phase reactant" of claim 61 defined as containing an "antigen" as one component of a specific binding pair, see Caldwell et al ('503), col. 16, lines 28-36) or constitute obvious variations in parameters which are routinely modified in the art {e.g. conjugating PEG to a member of a specific binding pair prior to applying the conjugate to the surface (instant claim 63) versus forming the PEG conjugate in situ (Caldwell et al ('503), col. 17, lines 24-27)} and which have not been described as critical to the practice of the invention.

**17)** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached at (703) 305-3399. The fax phone number for responses to be filed BEFORE final rejection is (703) 872-9306. The fax phone number for responses to be filed AFTER final rejection is (703) 872-9307.

Questions which are NOT RELATED TO THE EXAMINATION ON THE MERITS, should be directed to **TC 1600 CUSTOMER SERVICE at (703) 308-0198**. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

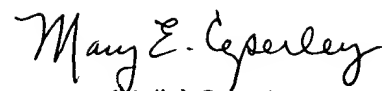


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January 23, 2003

A handwritten signature in cursive script, reading "Mary E. Ceperley".

Mary E. (Molly) Ceperley  
Primary Examiner  
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